08 CV 00875

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Attorneys for Plaintiff
ORGANOGENESIS, INC.

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

ORGANOGENESIS, INC.,

Plaintiff,

-against-

ADVANCED BIOHEALING, INC.,

Defendant.

Civil Action No.
Hon.

COMPLAINT

JURY TRIAL DEMANDED

Plaintiff Organogenesis, Inc. ("OI"), by and through its undersigned counsel, files this Complaint against Defendant Advanced BioHealing, Inc. ("Advanced BioHealing"), for monetary and injunctive relief. For its causes of action, OI alleges as follows:

INTRODUCTION

1. By this action, OI seeks to protect its customers, its business, and the public health from a misleading, false, malicious, and defamatory campaign launched by Advanced BioHealing and directed to OI's customers and potential customers, which include physicians, podiatrists, hospitals, and wound care treatment centers and clinics.

2. Advanced BioHealing has engaged in conduct specifically designed to unlawfully denigrate OI. More specifically, Advanced BioHealing has and continues to improperly disseminate a product recall letter prepared by OI to OI's physician customers who are not

affected by the product recall, while at the same time falsely and misleadingly advertising the purported benefits of Advanced BioHealing's competing product. Advanced BioHealing's campaign has caused confusion and panic among OI's customers and is interfering with OI's administration of its product recall.

3. Accordingly, this is an action for false advertising under the Lanham Act, 15 U.S.C. § 1051, *et. seq.*, and tortious interference with prospective economic advantage.

JURISDICTION AND VENUE

4. This action arises under the Lanham Act, 15 U.S.C. § 1125(a). This Court has jurisdiction over the claims in this action pursuant to 15 U.S.C. § 1121 and 28 U.S.C. §§ 1331 and 1367.

5. The amount in controversy exceeds the sum or value of $75,000, exclusive of interest and costs, and the parties are between citizens of different states. Therefore, subject matter jurisdiction is also conferred upon this Court pursuant to 28 U.S.C. § 1332.

6. On information and belief, Advanced BioHealing is engaged in acts and a regular course of conduct in New York in connection with the transactions and events alleged in this Complaint. Moreover, Advanced BioHealing has acted to cause tortious injury in New York by acts inside of and outside of the state. Advanced BioHealing also has offices in this district.

7. Advanced BioHealing's false and malicious advertising and marketing campaign was and continues to be targeted to OI's customers in the State of New York, among other states, and was sent to OI's customers in the State of New York. Advanced BioHealing also has offices Venue is proper, therefore, in this district pursuant to 28 U.S.C. §1391(b) and (c).

PARTIES

8. Plaintiff OI is a Delaware corporation with its principal place of business at 350 Dan Road, Canton, Massachusetts 02021. OI manufactures and distributes multiple bio-therapeutics for various medical conditions, including bio-active wound care products.

9. Upon information and belief, Advanced BioHealing is a Delaware corporation with its principal place of business located at 10933 N. Torrey Pines Road, Suite 200, La Jolla, California 92037. Advanced BioHealing, upon information and belief, has research and development offices located in this district at 347 Fifth Avenue, Suite 1407, New York, New York 10016.

BACKGROUND

10. OI was founded in 1985. OI is a pioneer in the field of regenerative medicine and is a leading regenerative medicine company. It researches, develops, and commercializes regenerative medicine technologies to deliver living, cell-based products to stimulate the body's natural healing process and activate the body's ability to repair and regenerate.

11. OI is the manufacturer, distributor, and owner of all rights in Apligraf® ("Apligraf"). Apligraf is biological tissue derived from human skin cells that, similar to human skin, contains two types of cells – an outer layer of protective skin cells (epidermal cells), and an inner layer of cells (dermal cells), both of which contain proteins and other substances that initiate the healing process. Apligraf is able to help heal and repair chronic sores and regenerate skin by stimulating the body's healing process. It delivers these biological healing substances (living cells and active proteins) directly into the wound thereby starting the healing cycle.

12. After years of research and development, in 1998, OI received the first ever Food and Drug Administration ("FDA") approval for a manufactured living cell-based therapy,

Apligraf, intended for the treatment of venous leg ulcers. In 2000, FDA approved Apligraf for the treatment of diabetic foot ulcers. Currently, Apligraf is the only bio-active product that is approved by the FDA to treat both chronic diabetic foot ulcers and venous leg ulcers.

13. Diabetic foot ulcers and venous leg ulcers are conditions that often affect the elderly, Type II diabetics, or patients suffering from peripheral vascular disease. Apligraf has been hailed a miracle of science and has changed the lives of patients suffering from such chronic skin ulcers. Prior to Apligraf, skin ulcers that would not respond to traditional wound treatment would often progress to a limb amputation or life threatening condition. Apligraf has not only helped improve a patient's quality of life, but in many cases, it has saved a patient who otherwise may have lost a limb or succumbed to a life-threatening infection.

14. Apligraf is a prescription product that must be applied directly to a wound by a medical professional.

15. OI has invested significant resources towards building a highly skilled sales and marketing organization dedicated to Apligraf. To date, over 200,000 units of Apligraf have been applied to patients.

15. Apligraf customers primarily consist of physicians, podiatrists, hospitals, and wound care treatment centers and clinics.

16. Advanced BioHealing, upon information and belief, distributes and sells Dermagraft®, a product used for the treatment of wounds such as certain diabetic foot ulcers and wounds associated with dystrophic epidermolysis bullosa. Upon information and belief, Dermagraft is not FDA approved for the treatment of venous leg ulcers.

17. Advanced BioHealing's Dermagraft® product ("Dermagraft") is directly competitive with OI's Apligraf® ("Apligraf") product.

The Apligraf Recall

18. In December 2007, OI learned that a total of 177 distributed Apligraf units were potentially contaminated (the "Affected Apligraf Units").

19. Upon learning of the potential contamination, OI promptly designed and implemented a recall procedure for the Affected Apligraf units in consultation with the Food and Drug Administration (the "Apligraf Recall").

20. In conducting the Apligraf Recall, OI identified all customers who had received the Affected Apligraf Units. OI then contacted only those customers who received the Affected Apligraf Units to ensure OI's ability to properly and effectively track the Apligraf Recall.

21. OI sent a letter to each of its customers who had received the Affected Apligraf Units (the "Apligraf Recall Letter"). The Apligraf Recall Letter discloses the reason and clinical implications for the Apligraf Recall, provides contact information in the event of questions, and requests that the recipient provide OI with written confirmation of receipt of the Apligraf Recall Letter. A copy of the Apligraf Recall Letter is attached as Complaint Exhibit 1.

22. The Apligraf Recall Letter makes it clear that it is only being sent to Apligraf customers who received the Affected Apligraf Units. *See* Exhibit 1.

Advanced BioHealing's False and Misleading Advertisements

23. On or about January 8, 2008, Advanced BioHealing sent out an electronic mail communication to at least one physician in the New York area (the "Advanced BioHealing Communication"). A copy of the Advanced BioHealing Communication is attached as Complaint Exhibit 2 and is incorporated herein.

24. The Advanced BioHealing Communication, which was sent by Advanced BioHealing to wound-care providers, states:

Wound Care Provider,

I am sending a safety notification to all wound care providers that use multiple advanced wound care products in their practice. (Letter attached) This letter was sent directly from Organogenesis to many of their Apligraf customers throughout the country, but evidently not everyone. The letter outlines specific instructions to the physician. I am sending this letter in hopes that none of the contaminated Apligraf was applied to your patients.

A reminder Dermagraft is the only cyro-preserved human-derived dermal substrate available. The advantages of cyro-preservation over the rest of the products out there are countless. Most importantly, Dermagraft goes through 14 day sterile testing by the FDA before it is shipped. This leaves no chance for contamination and 100% confidence in safety for your patients' wounds.

Proprietary cryopreservation process ensures confidence
Dermagraft is cryopreserved to allow long-term maintenance of tissue integrity and cellular viability. Cryopreservation of Dermagraft offers a number of additional product benefits:

- Allows for safety testing prior to shipping and application
- Provides longer shelf life—long-term storage (up to 6 months) when stored at -75°C ± 10°C

There have been no reported immunological responses or rejections from patients that received Dermagraft.

Andrew Sole
Advanced Technolgy Specialist-New York
Advanced BioHealing, Inc.
Direct: 732 991-3610
Email: <mailto:lmyers@advancedbiohealing.com> asole@advancedbiohealing.com
Orders: 1-877-DERMAGRAFT (877-337-6247)

25. OI obtained a copy of the Advanced BioHealing Communication from two physicians located in New York on or about January 9, 2008.

26. Upon information and belief, Advanced BioHealing also sent out the Advanced BioHealing Communication to physicians and other wound care professionals by electronic mail message, facsimile or other means throughout the United States, including Florida, Michigan, New York, and Virginia.

27. Upon information and belief, in addition to circulating the Advanced BioHealing Communication by electronic mail message, Advanced BioHealing has also sent its

representatives to a number of wound care treatment centers to disseminate the Advanced BioHealing Communication in person to physicians and nurses.

28. Additionally, Apligraf customers have reported to OI that Advanced BioHealing sales representatives have made various oral statements to Apligraf customers consistent with the Advanced BioHealing Communication.

29. Upon learning of the Advanced BioHealing Communication, OI immediately advised Advanced BioHealing of the false claims contained in the Advanced BioHealing Communication and requested that Advanced BioHealing stop further dissemination of the Advanced BioHealing Communication. A copy of OI's request is attached hereto as Exhibit 3.

30. Initially, Advanced BioHealing stated that it would investigate OI's claims. A copy of Advanced BioHealing's response is attached hereto as Exhibit 4.

31. Later, on or about January 14, 2008, Advanced BioHealing indicated that it had ceased disseminating communications regarding the Apligraf Recall as of January 9 or 10, 2008.

ADVANCED BIOHEALING CONTINUES AND ESCALATES ITS WRONGFUL CONDUCT

32. On or about January 16, 2008, OI learned that Advanced BioHealing may not have ceased disseminating communications regarding the Apligraf Recall.

33. More specifically, OI received an electronic mail message from one of its customers that appeared to indicate that an Advanced BioHealing employee, Carol Gray, was attempting to recall an electronic mail message on January 14, 2008.

34. OI promptly contacted Advanced BioHealing through counsel. A copy of OI's correspondence to Advanced BioHealing's counsel is attached as Exhibit 5.

35. In response, Advanced BioHealing assured OI, in writing, that it notified its sales force to cease sending communications regarding the Apligraf Recall as of January 11, 2008.

36. On January 18, 2008, OI learned definitively that Advanced BioHealing had not ceased disseminating communications regarding the Apligraf Recall as of January 9, 10 or 11, 2008 despite Advanced BioHealing's representations to the contrary.

37. OI learned that on or about January 14, 2008, Advanced BioHealing sent out another electronic mail communication to OI's customers and other wound-care providers (the "Additional Advanced BioHealing Communication"). A copy of the electronic mail message is attached as Exhibit 6 and is incorporated herein.

38. The Additional Advanced BioHealing Communication contained the subject line "Copy of the Recent Apligraf Recall Letter, Unparalled [sic] Safety Profile of Dermagraft" and stated as follows:

Keeping You Informed:

Attached is the letter announcing the recent Apligraf recall from Organogenesis. Apligraf recalls have happened many times. (as reported to the FDA and documented on the FDA website).

Dermagraft has an unparalleled safety profile:

Advanced Biohealing, Inc. will not send any Dermagraft to customers, for use on their patients, until the End of Production- USP Sterility Data Testing Results are completed (conducted by an independent laboratory):

~end of production USP Sterility Safety testing is a requirement *before* patient application with Dermagraft. Dermagraft has a 5 month shelf life.

~end of production USP Sterility Safety testing results for Apligraf are not obtained until *after* application to patients receiving Apligraf. This may put patients and their providers at risk.

Apply Dermagraft with confidence! Safety Unparalleled!

Carol Gray
Advanced Technology Specialist
Mobile: 443 306 4762
EMail: cgray@advancedbiohealing.com

39. OI obtained a copy of the Additional Advanced BioHealing Communication from one of its Apligraf customers.

The Misleading and False Claims

40. The Advanced BioHealing Communication misleadingly implies that OI selectively and improperly sent out the Apligraf Recall Letter to only certain physicians. The Advanced BioHealing Communication can be read to further imply that OI is purposefully attempting to conceal the Apligraf Recall.

41. This claim is false and misleading because OI properly sent out the Apligraf Recall Letter to those physicians who received Apligraf units specifically affected by the Apligraf Recall.

42. The Advanced BioHealing Communication claims that "the advantages of cyro-preservation over the rest of the products out there are countless. Most importantly, Dermagraft goes through 14 day sterile testing by the FDA before it is shipped. This leaves no chance for contamination and 100% confidence in safety for your patients' wounds."

43. These claims are false because the FDA does not conduct sterility testing or any type of testing. The claims also imply that FDA is involved in the Dermagraft manufacturing process, and that Apligraf somehow fails to meet FDA standards. Similarly, these claims and/or suggestions are false.

44. Advanced BioHealing's claim that Dermagraft "leaves no chance for contamination and 100% confidence in safety for your patients' wounds" is also false for an additional reason. This claim is false because Dermagraft underwent a recall in 1998 for endotoxin levels that did not meet FDA standards and a 2003 recall for distributed product that did not meet specifications. *See* FDA Enforcement Report dated May 20, 1998 for Dermagraft and a related product, Dermagraft-TC, attached as Exhibit 7. *See also* FDA Enforcement Report dated June 11, 2003 for Dermagraft attached as Exhibit 8.

45. The Advanced BioHealing Communication claims that cyro-preservation of Dermagraft "allows for safety testing prior to shipping and application". This claim misleadingly implies that Apligraf is not safety tested prior to release.

46. Upon information and belief, to date, Advanced BioHealing has disseminated the Advanced BioHealing Communication to OI's Apligraf customers in Florida, Michigan, New York, and Virginia.

47. Further, upon information and belief, Advanced BioHealing's sales representatives also have made in-person visits and telephone calls to OI's Apligraf customers throughout the country to follow-up on the Advanced BioHealing Communication.

The Confusion Caused by the False and Misleading Claims

48. Advanced BioHealing clearly prepared and sent the Advanced BioHealing Communication to Apligraf customers and prospective Apligraf customers.

49. Many Apligraf customers not affected by the Apligraf Recall contacted OI and expressed great concern and confusion regarding whether their patients were affected by the Apligraf Recall.

50. OI's Apligraf sales force also learned that the Advanced BioHealing Communication "caused panic" as some nurses frantically pulled charts for their patients to ensure that they were not affected by the Apligraf Recall.

51. Other Apligraf customers have questioned and expressed confusion as to whether their patients were impacted by the Apligraf Recall.

52. OI has also received a number of comments and inquiries from Apligraf customers who had received the Advanced BioHealing Communication.

53. Due to confusion associated with the Advanced BioHealing Communication, OI had to provide two of the largest national wound care chains, with hundreds of facilities across the United States, with clarification of the Apligraf Recall including a written summary of the Apligraf Recall, a summary of OI's actions with respect to the Apligraf Recall, and an explanation of the relevance of the Advanced BioHealing Communication to the Apligraf Recall.

54. Upon information and belief, the Additional Advanced BioHealing Communication has also caused confusion among OI's customers and has damaged OI's relationships with consumers by suggesting that Apligraf is not safety-tested prior to distribution.

55. The Advanced BioHealing Communication has caused a strain on Apligraf's relationships with its valued customers, who have demonstrated loyalty to Apligraf.

56. Advanced BioHealing's actions have also interfered with OI's administration of the Apligraf Recall.

COUNT ONE: EXPRESSLY FALSE ADVERTISING UNDER SECTION 43(A) OF THE LANHAM ACT

57. The preceding factual allegations set forth in this Complaint are incorporated and alleged in this Count as if fully set forth herein.

58. This claim for false advertising arises under § 43(a) of the Lanham Act, 15 U.S.C. § 1125(a).

59. The Advanced BioHealing Communication contains false or misleading statements or claims as alleged above.

60. The Advanced BioHealing Communication falsely claims that "the advantages of cryro-preservation over the rest of the products out there are countless. Most importantly, Dermagraft goes through 14 day sterile testing by the FDA before it is shipped. This leaves no

chance for contamination and 100% confidence in safety for your patients' wounds." These claims are false because the FDA does not conduct sterility testing or any type of testing.

61. Advanced BioHealing's claim that Dermagraft "leaves no chance for contamination and 100% confidence in safety for your patients' wounds" is also false. This claim is false because Dermagraft underwent a recall in 1998 for endotoxin levels that did not meet FDA standards and a 2003 recall for distributed product that did not meet specifications.

62. The false and misleading representations made by Advanced BioHealing have appeared in commercial advertising or promotion, namely in direct e-mail solicitations to OI's customers in several states and are, therefore, in interstate commerce.

63. Advanced BioHealing's false and misleading advertising claims are material to consumers' purchasing decisions.

64. As a result of Advanced BioHealing's intentional, deliberate, and willful actions, OI has suffered and will continue to suffer irreparable injury, the exact nature and extent of which cannot be ascertained at this time, and for which there is no adequate remedy at law.

COUNT TWO:
IMPLIEDLY FALSE ADVERTISING UNDER SECTION 43(A) OF THE LANHAM ACT

65. The preceding factual allegations set forth in this Complaint are incorporated and alleged in this Count as if fully set forth herein.

66. This claim for false advertising arises under § 43(a) of the Lanham Act, 15 U.S.C. § 1125(a).

67. The Advanced BioHealing Communication contains or implies numerous false or misleading statements or claims as alleged above.

68. The Advanced BioHealing Communication misleadingly implies that OI selectively sent out the Apligraf Recall Letter to certain physicians. This claim is false and misleading because OI sent out the Apligraf Recall Letter to those physicians who received Apligraf units specifically affected by the Apligraf Recall.

69. The Advanced BioHealing Communication claims that cryo-preservation of Dermagraft "allows for safety testing prior to shipping and application." This claim misleadingly implies that Apligraf is not safety tested prior to release.

70. The Advanced BioHealing Communication falsely claims that "the advantages of cryro-preservation over the rest of the products out there are countless. Most importantly, Dermagraft goes through 14 day sterile testing by the FDA before it is shipped. This leaves no chance for contamination and 100% confidence in safety for your patients' wounds." This claim is false because it implies that the FDA is involved in the Dermagraft manufacturing process, and that Apligraf somehow fails to meet FDA standards.

71. The Additional Advanced BioHealing Communication falsely implies that Apligraf is not safety-tested prior to distribution.

72. The false and misleading representations made by Advanced BioHealing have appeared in commercial advertising or promotion, namely on direct e-mail solicitations to OI's customers in several states and are, therefore, in interstate commerce.

73. Advanced BioHealing's false and misleading advertising claims are material to consumers' purchasing decisions.

74. As a result of Advanced BioHealing's intentional, deliberate, and willful actions, OI has suffered and will continue to suffer irreparable injury, the exact nature and extent of which cannot be ascertained at this time, and for which there is no adequate remedy at law.

COUNT THREE:
TORTIOUS INTERFERENCE WITH PROSPECTIVE ECONOMIC ADVANTAGE

75. The preceding factual allegations set forth in this Complaint are incorporated and alleged in this Count as if fully set forth herein.

76. Prior to the acts complained of herein, Advanced BioHealing had full knowledge of the fact that OI has economic relationships with customers and that these relationships provide OI with a probability of future economic benefit.

77. Advanced BioHealing has wrongfully, intentionally and maliciously interfered with OI's prospective economic advantage by engaging in a campaign of disparagement, misrepresentation and deception with an intent to injure OI and with an intent to disrupt OI's relationships.

78. The conduct of Advanced BioHealing resulted in an actual disruption of OI's relationships, and but for Advanced BioHealing's conduct such disruption would not have occurred, and said conduct has caused OI irreparable injury, loss of reputation and pecuniary damages for which OI is entitled to compensation.

PRAYERS FOR RELIEF

WHEREFORE, the Plaintiff, Organogenesis, Inc., requests the following relief from the Court:

a. The Court should temporarily, preliminarily, and permanently enjoin Advanced BioHealing, its officers, agents, servants, employees, and its attorneys, and all those acting in active concert or participation therewith, from sending, transmitting, or communicating the Advanced BioHealing Communication or the Additional Advanced BioHealing Communication to individuals or entities whatsoever, including OI's customers;

b. The Court should temporarily, preliminarily, and permanently enjoin Advanced BioHealing, its officers, agents, servants, employees, and its attorneys, and all those acting in active concert or participation therewith who receive actual notice of the Order by personal service or otherwise, from making false and misleading claims regarding the recall of OI's Apligraf product, and claiming or implying that the Apligraf product is of low quality or lesser quality than Advanced BioHealing's Dermagraph product;

c. The Court should temporarily, preliminarily, and permanently enjoining Advanced BioHealing, its officers, agents, servants, employees, and its attorneys, and all those acting in active concert or participation therewith, from sending, transmitting, or communicating the Apligraf Recall Letter to any individuals or entities;

d. The Court should temporarily, preliminarily, and permanently enjoin Advanced BioHealing from interfering with the administration of the Apligraf Recall;

e. The Court should temporarily, preliminarily, and permanently enjoin Advanced BioHealing, its officers, agents, servants, employees, and its attorneys, and all those acting in active concert or participation therewith, from sending, transmitting or engaging in any other negative or disparaging communications regarding the Apligraf Recall;

f. The Court should temporarily, preliminarily, and permanently enjoin Advanced BioHealing, its officers, agents, servants, employees, and its attorneys, and all those acting in active concert or participation therewith from disseminating or engaging in any other false, negative or disparaging communications regarding Apligraf;

g. The Court should temporarily, preliminarily, and permanently enjoin Advanced BioHealing, its officers, agents, servants, employees, and its attorneys, and all those acting in

active concert or participation therewith from disseminating or engaging in any negative or disparaging communications regarding Apligraf and the Apligraf Recall;

h. The Court should order Advanced BioHealing to provide contact information for and identify all recipients of communications it sent regarding Apligraf and the Apligraf Recall so that OI may disseminate corrective statements to ensure that all false, misleading, and deceptive statements made with respect to OI are retracted and corrected;

i. The Court should enter judgment against Advanced BioHealing and in favor of OI for the damages allowable under applicable law, together with any multipliers allowed by law;

j. The Court should require Advanced BioHealing to pay to OI the costs, expenses, and reasonable attorney's fees for the prosecution of this action;

k. The Court should grant OI such other relief in law or in equity as the Court deems just and proper.

JURY DEMAND

OI requests trial by jury on all issues so triable.

Dated: January 24, 2008
New York, New York

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New York, NY 10019
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FAX (212) 484-3990

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Of Counsel
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Savalle C. Sims, Esq.

Ross Q. Panko, Esq.
ARENT FOX LLP
1050 Connecticut Avenue, N.W.
Washington, DC 20036
(202) 857-6000

Exhibit 1

Organogenesis inc.
LIVING TECHNOLOGY
150 Dan Road, Canton, Massachusetts 02021

December 27, 2007

Subject: Potential contaminated Apligraf Units manufactured by Organogenesis Inc.

Dear Doctor:

This letter is intended to inform you of important information regarding Apligraf units shipped to you on December 14 or 17, 2007. This involves units from Apligraf **Lot Number GS0711.20.01.2A. You have received Apligraf unit(s) from this Lot.**

Description of Issue
Apligraf Lot **Number GS0711.20.01.2A** was reported to have contamination in the agarose nutrient medium of some units retained at Organogenesis. Colonies were visually observed within the agarose. Preliminary microbiological testing identified the bacterial contaminant as a gram positive rod (bacillus) organism. A definitive identification of the organism will be provided to you by fax as soon as available.

Product Disposition
According to our records, your procedure date(s) for Apligraf from this Lot has already occurred and the product has likely been applied to a patient(s). If you *have not* applied the affected unit(s) to a patient, you should return unused product to Organogenesis Inc. for investigation. Information on product return can be obtained by contacting Organogenesis at the number below. Please maintain accurate and complete records of all returns and their disposition.

Clinical Implications
While the unit(s) you have received may not be contaminated, all standard wound care precautions should be used to assure the safety of the patient. If the affected units had been applied to a patient, it is recommended that you monitor the patient closely for any potential adverse events. Organogenesis recommends careful assessment of possible infection by observing for signs and symptoms of infection as well as treatment per your clinical discretion. Treatment options at your clinical

discretion include topical antibiotics, oral antibiotics or Apligraf removal. We hope that this information is helpful in managing care for your patient.

The quality of Apligraf and its safety are of the highest priority to Organogenesis. We are committed to providing complete information in a timely fashion and will contact you for patient follow up and reports of any adverse events that may have resulted subsequent to this Apligraf treatment.

In addition to this faxed letter, we are attempting to contact you by phone to provide information on this Apligraf Lot. **Although we will be attempting to contact you by phone today, it will be most efficient if you can contact us at 1 888 432-5232, Option # 2 (Medical Inquiries).**

To confirm receipt of this important communication, please sign and fax back this form to us at 781-401-1288.

Sincerely,

Patrick Bilbo
Vice President, Regulatory Affairs
(781) 401-1155

Recipient Signature: _____

Recipient Name: _____

PLEASE RETURN THIS LETTER SIGNED TO FAX #781-401-1288

Exhibit 2

Attachments: 20080107053634.pdf

20080107053634.pdf (57 KB)

-----Original Message-----
From: "Andrew Sole" <asole@advancedbiohealing.com>

Date: Tue, 8 Jan 2008 20:30:42
To:undisclosed-recipients:;
Subject: Apligraf Recall Letter

Wound Care Provider,

I am sending a safety notification to all wound care providers that use multiple advanced wound care products in their practice. (Letter attached) This letter was sent directly from Organogenesis to many of their Apligraf customers throughout the country, but evidently not everyone. The letter outlines specific instructions to the physician. I am sending this letter in hopes that none of the contaminated Apligraf was applied to your patients.

A reminder Dermagraft is the only cyro-preserved human-derived dermal substrate available. The advantages of cyro-preservation over the rest of the products out there are countless. Most importantly, Dermagraft goes through 14 day sterile testing by the FDA before it is shipped. This leaves no chance for contamination and 100% confidence in safety for your patients' wounds.

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Orders: 1-877-DERMAGRAFT (877-337-6247)

Organogenesis inc.
LIVING TECHNOLOGY
150 Dan Road, Canton, Massachusetts 02021

December 27, 2007

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discretion include topical antibiotics, oral antibiotics or Apligraf removal. We hope that this information is helpful in managing care for your patient.

The quality of Apligraf and its safety are of the highest priority to Organogenesis. We are committed to providing complete information in a timely fashion and will contact you for patient follow up and reports of any adverse events that may have resulted subsequent to this Apligraf treatment.

In addition to this faxed letter, we are attempting to contact you by phone to provide information on this Apligraf Lot. **Although we will be attempting to contact you by phone today, It will be most efficient if you can contact us at 1 888 432-5232, Option # 2 (Medical Inquiries).**

To confirm receipt of this important communication, please sign and fax back this form to us at 781-401-1288.

Sincerely,

Patrick Bilbo
Vice President, Regulatory Affairs
(781) 401-1155

Recipient Signature: _____

Recipient Name: _____

PLEASE RETURN THIS LETTER SIGNED TO FAX #781-401-1288

Exhibit 3

Arent Fox

James R. Ravitz
Attorney
202.857.8903 DIRECT
202.857.6395 FAX
ravitz.james@arentfox.com

January 9, 2008

VIA FACSIMILE AND FEDERAL EXPRESS

Mr. Kevin Rakin
Chief Executive Officer
Advanced BioHealing, Inc.
Suite 200
10933 North Torrey Pines Road
La Jolla, CA 92037

Re: Apligraf®

Dear Mr. Rakin,

This firm represents Organogenesis, Inc. (OI). As you are undoubtedly aware, OI is the manufacturer, distributor, and owner of all rights in Apligraf® (Apligraf), an advanced wound healing product. As you also know, OI is currently undertaking a relatively limited recall regarding certain Apligraf units (the Apligraf Recall).

OI recently learned, through numerous reports from physicians that Advanced BioHealing, Inc. (ABH) has sent at least one improper and unlawful written communication regarding Apligraf to a number of physicians. We refer, in particular, to the enclosed electronic mail message (with attachment) that Andrew Sole, an ABH sales representative, sent to an undisclosed number of recipients on January 8, 2008 (the ABH Communication). We assume that the ABH Communication was sent not only to physicians who currently use Apligraf, but also to all physicians who treat wounds. In addition, we have received other similar reports across the country concerning verbal statements by ABH to physicians along the same lines as the ABH Communication.

The ABH Communication is clearly designed to unlawfully denigrate Apligraf, unlawfully promote ABH's product Dermagraft, unlawfully interfere with OI's current and prospective business relationships, and improperly interfere with the Apligraf Recall. This

Arent Fox

intention is evidenced by the false, disparaging, and defamatory statements contained in the ABH Communication that we believe violate not only the Federal Food, Drug, and Cosmetic Act, but also various federal and state advertising laws. For instance, the ABH Communication implies that OI is concealing the Apligraf Recall from its customers and failing to conduct the Apligraf Recall in a compliant manner. This is misleading, false and disparaging.

ABH's statements regarding the alleged advantages of cryo-preservation over Apligraf with respect to potential contamination are also misleading and false. In addition to the 1998 Dermagraft recall for endotoxin contamination, the Food and Drug Administration's (FDA) MAUDE database reflects numerous instances of cases where people treated with Dermagraft developed post-implantation complications from the implant. Further, ABH's statement that "Dermagraft goes through 14 day sterility testing by the FDA before it is shipped" is also false. As you undoubtedly are aware, the FDA does not conduct sterility testing or any type of testing for that matter. Such statements are clearly designed and intended to negatively impact OI by misleading physicians into believing that the FDA is involved in the Dermagraft manufacturing process, and that Apligraf, in general, fails to meet FDA standards.

Additionally, ABH's statements that cryo-preservation "allows for safety testing prior to shipping and application" implies that Apligraf is not safety tested prior to release. This is not only false but is disparaging to OI and Apligraf.

Moreover, ABH's actions, which are designed to interfere with OI's ongoing and prospective business relationships, are interfering with OI's ability to conduct the Apligraf Recall. OI is working closely with the FDA to ensure that the Apligraf Recall is conducted in an appropriate and compliant manner. As a result of ABH's actions, however, OI has received several signed recall communications from physicians who did not receive the affected Apligraf unit. Based on information available to us, we believe that those physicians received the recall communication from ABH and were confused as to their responsibilities regarding the Apligraf Recall. Such interference is making it difficult for OI to properly implement and track the effectiveness of the recall. Thus, ABH's actions are significantly negatively impacting the effectiveness of the Apligraf Recall which creates a serious risk to the public health.

Accordingly, OI demands that ABH ***immediately*** cease and desist from interfering with the Apligraf Recall and from making any further false, disparaging, or defamatory statements regarding Apligraf; and that you confirm in writing no later than January 11, 2008, that you will cease your recent activities described herein. We further demand that you provide us with a list of all physicians and wound centers to which the ABH Communication was distributed. In the event that you fail to comply with these demands, OI reserves the right to pursue all legal remedies at its disposal to address ABH's activities. Notwithstanding, OI intends to notify the

Arent Fox

FDA regarding ABH's recent activities so that steps can be taken to minimize the harm that ABH has already caused to the Apligraf Recall from a public health standpoint.

Sincerely,

James R. Ravitz

Enclosure

cc: Mr. Geoff MacKay
Mr. Patrick R. Bilbo
Organogenesis, Inc.
Savalle Sims, Esq.
Arent Fox LLP

Attachments: 20080107053634.pdf

20080107053634.pdf (57 KB)

-----Original Message-----
From: "Andrew Sole" <asole@advancedbiohealing.com>

Date: Tue, 8 Jan 2008 20:30:42
To:undisclosed-recipients:;
Subject: Apligraf Recall Letter

Wound Care Provider,

I am sending a safety notification to all wound care providers that use multiple advanced wound care products in their practice. (Letter attached) This letter was sent directly from Organogenesis to many of their Apligraf customers throughout the country, but evidently not everyone. The letter outlines specific instructions to the physician. I am sending this letter in hopes that none of the contaminated Apligraf was applied to your patients.

A reminder Dermagraft is the only cyro-preserved human-derived dermal substrate available. The advantages of cyro-preservation over the rest of the products out there are countless. Most importantly, Dermagraft goes through 14 day sterile testing by the FDA before it is shipped. This leaves no chance for contamination and 100% confidence in safety for your patients' wounds.

Proprietary cryopreservation process ensures confidence
Dermagraft is cryopreserved to allow long-term maintenance of tissue integrity and cellular viability. Cryopreservation of Dermagraft offers a number of additional product benefits:

- Allows for safety testing prior to shipping and application
- Provides longer shelf life—long-term storage (up to 6 months) when stored at -75°C ± 10°C

There have been no reported immunological responses or rejections from patients that received Dermagraft.

Andrew Sole
Advanced Technolgy Specialist-New York
Advanced BioHealing, Inc.
Direct: 732 991-3610
Email: asole@advancedbiohealing.com
Orders: 1-877-DERMAGRAFT (877-337-6247)

Organogenesis inc.
LIVING TECHNOLOGY
150 Dan Road, Canton, Massachusetts 02021

December 27, 2007

Subject: Potential contaminated Apligraf Units manufactured by Organogenesis Inc.

Dear Doctor:

This letter is intended to inform you of important information regarding Apligraf units shipped to you on December 14 or 17, 2007. This involves units from Apligraf **Lot Number GS0711.20.01.2A. You have received Apligraf unit(s) from this Lot.**

Description of Issue
Apligraf **Lot Number GS0711.20.01.2A** was reported to have contamination in the agarose nutrient medium of some units retained at Organogenesis. Colonies were visually observed within the agarose. Preliminary microbiological testing identified the bacterial contaminant as a gram positive rod (bacillus) organism. A definitive identification of the organism will be provided to you by fax as soon as available.

Product Disposition
According to our records, your procedure date(s) for Apligraf from this Lot has already occurred and the product has likely been applied to a patient(s). If you *have not* applied the affected unit(s) to a patient, you should return unused product to Organogenesis Inc. for investigation. Information on product return can be obtained by contacting Organogenesis at the number below. Please maintain accurate and complete records of all returns and their disposition.

Clinical Implications
While the unit(s) you have received may not be contaminated, all standard wound care precautions should be used to assure the safety of the patient. If the affected units had been applied to a patient, it is recommended that you monitor the patient closely for any potential adverse events. Organogenesis recommends careful assessment of possible infection by observing for signs and symptoms of infection as well as treatment per your clinical discretion. Treatment options at your clinical

discretion include topical antibiotics, oral antibiotics or Apligraf removal. We hope that this information is helpful in managing care for your patient.

The quality of Apligraf and its safety are of the highest priority to Organogenesis. We are committed to providing complete information in a timely fashion and will contact you for patient follow up and reports of any adverse events that may have resulted subsequent to this Apligraf treatment.

In addition to this faxed letter, we are attempting to contact you by phone to provide information on this Apligraf Lot. **Although we will be attempting to contact you by phone today, It will be most efficient if you can contact us at 1 888 432-5232, Option # 2 (Medical Inquiries).**

To confirm receipt of this important communication, please sign and fax back this form to us at 781-401-1288.

Sincerely,

Patrick Bilbo
Vice President, Regulatory Affairs
(781) 401-1155

Recipient Signature: _____

Recipient Name: _____

PLEASE RETURN THIS LETTER SIGNED TO FAX #781-401-1288

Exhibit 4

Holland & Knight

Tel 202 955 3000
Fax 202 955 5564

Holland & Knight LLP
2099 Pennsylvania Avenue, N.W., Suite 100
Washington, D.C. 20006-6801
www.hklaw.com

CHARLES D. TOBIN
(202) 419-2539
ctobin@hklaw.com

January 11, 2008

Via Facsimile And U.S. Mail

James R. Ravitz, Esq.
Arent Fox LLP
1050 Connecticut Avenue, N.W.
Washington, DC 20036-5339

Re: Your letter to Advanced BioHealing, Inc.

Dear Mr. Ravitz:

We are counsel to Advanced BioHealing, Inc. Our client referred to me your January 9, 2008 letter, which you sent on behalf of your client Organogenesis, Inc.

We are reviewing this matter carefully with Advanced BioHealing and will respond to your letter substantively by no later than Friday, January 18.

In the meanwhile please feel free to contact me if there's anything further you would like to discuss.

Very truly yours,

HOLLAND & KNIGHT LLP

Charles D. Tobin

cc: Mr. Kevin Rakin
Michael M. Gaba, Esq.

CDT:hjc # 5049957_v1

Exhibit 5

Arent Fox

January 16, 2008

Savalle C. Sims
Attorney
202.857.8948 DIRECT
202.857.6395 FAX
sims.savalle@arentfox.com

VIA FACSIMILE AND FIRST CLASS MAIL

Charles D. Tobin, Esquire
Holland & Knight
2099 Pennsylvania Avenue, N.W., Suite 100
Washington, D.C. 20004-4801

Re: Advanced BioHealing, Inc.

Dear Chuck:

I write in furtherance of our letter to your client, Advanced BioHealing, Inc. ("Advanced BioHealing") dated January 9, 2008 and this firm's recent discussions with you concerning Advanced BioHealing's recent communications regarding Apligraf and OI's recent Apligraf recall (the "Apligraf Recall").

During our recent discussions, you told us that Advanced BioHealing had ceased disseminating communications regarding the Apligraf Recall ("Advanced BioHealing Communications") while the parties discuss a global resolution of this matter. More specifically, we understood from you that Advanced BioHealing had ceased disseminating the Advanced BioHealing Communications upon receipt of Mr. Ravitz's January 9, 2008 letter to Kevin Rakin, Advanced BioHealing's Chief Executive Officer.

As I shared with you earlier this week, we believe that Advanced BioHealing's dissemination of communications regarding the Apligraf Recall are not limited to communications initiated by Andrew Sole and extend *far* beyond the New York area. As we discussed, Advanced BioHealing's immediate halt of the complained of conduct is of particular importance to OI because Advanced BioHealing's actions are interfering with the Apligraf Recall.

Just today, OI shared with us a troubling communication evidencing that Advanced BioHealing continues to disseminate the Advanced BioHealing Communications despite its representations to the contrary. I refer in particular to the electronic mail message that Carol Gray, an Advanced BioHealing employee sent to one of OI's Apligraf customers located in Richmond, Virginia ***"Re Recall: Copy of the Recent Apligraf Recall Letter, Unparalled Safety Profile of Dermagraft"***. Additionally, an Apligraf customer in Michigan informed OI today that she received the enclosed facsimile on January 10, 2008. At a minimum, the enclosed communications evidence that (1) the Advanced BioHealing Communications are emanating from more than a single employee; (2) the Advanced BioHealing Communications are *not* limited to the New York area;

1050 Connecticut Avenue, NW
Washington, DC 20036-5339
T 202.857.6000 F 202.857.6395

1675 Broadway
New York, NY 10019-5820
T 212.484.3900 F 212.484.3990

555 West Fifth Street, 48th Floor
Los Angeles, CA 90013-1065
T 213.629.7400 F 213.629.7401

Arent Fox

and (3) Advanced BioHealing continues to disseminate the Advanced BioHealing Communications despite its interim agreement not to do so.

OI views these latest developments as particularly egregious given your client's assurances that it had ceased and desisted the complained of conduct. Advanced BioHealing's conduct calls into question the spirit in which it has approached the parties' recent settlement discussions. More importantly, we question with new skepticism Advanced BioHealing's reluctance to provide OI with information that it needs to minimize the harm and confusion that Advanced BioHealing has caused to the Apligraf Recall from a public health standpoint.

Clearly, your client's unwritten assurances are no longer sufficient. Accordingly, we request that Advanced BioHealing provide in writing today assurances that it will cease and desist disseminating statements regarding Apligraf and the Apligraf Recall while the parties' settlement discussions are ongoing.

Sincerely,

Savalle C. Sims

Enclosures
cc: James Ravitz, Esquire
Mr. Geoff MacKay
Mr. Patrick R. Bilbo

From: Limor Glazer-Schwam [mailto:limor.glazerschwam@verizon.net]
Sent: Tuesday, January 15, 2008 11:40 PM
To: Stephen Rowe
Subject: FW: Recall: Copy of the Recent Apligraf Recall Letter, Unparalled Safety Profile of Dermagraft.

Note my response to her shameful behavior.

From: Carol Gray [mailto:cgray@advancedbiohealing.com]
Sent: Monday, January 14, 2008 11:39 PM
To: Limor Glazer-Schwam
Subject: RE: Recall: Copy of the Recent Apligraf Recall Letter, Unparalled Safety Profile of Dermagraft.

I would like to send my apology to you. I tried to recall any email that was not received as you can see below.

From: Limor Glazer-Schwam [mailto:limor.glazerschwam@verizon.net]
Sent: Monday, January 14, 2008 10:29 PM
To: Carol Gray
Subject: RE: Recall: Copy of the Recent Apligraf Recall Letter, Unparalled Safety Profile of Dermagraft.

Shame on you.

From: Carol Gray [mailto:cgray@advancedbiohealing.com]

Sent: Monday, January 14, 2008 9:10 PM
Subject: Recall: Copy of the Recent Apligraf Recall Letter, Unparalled Safety Profile of Dermagraft.

Carol Gray would like to recall the message, "Copy of the Recent Apligraf Recall Letter, Unparalled Safety Profile of Dermagraft.".

ST MARY MERCY HOSPITAL
A MEMBER OF TRINITY HEALTH
Livonia, MI 48154
P 734-655-4800
www.stmarymercy.org

FAX

Date: 1/16/08 **Pages:** 3

To: Caroline Curtis **From:** Wound Care Center Lorraine

Phone: **Phone:** (734) 655-3800

Fax: (781) 401-1288 **Fax:** (734) 655-3810

Re:

☐ **Urgent** ☒ **For Review** ☐ **Please Comment** ☐ **Please Reply** ☐ **Please Recycle**

• **Comments**

Per our phone conversation, this is the faxed notification we received on 1/10/08.

Thanks
Lorraine

1/16/08: Lorraine Getkin, RN OC stated she received this fax on Jan 10, 9:50

Vision Statement
To be a truly great hospital, providing comprehensive, coordinated, and compassionate care, every time to everyone

National Committee for Quality Health Care
2004 Award Winner

✓ mary Gilbertson sent

Organogenesis Inc.
LIVING TECHNOLOGY
160 Dan Road, Canton, Massachusetts 02021

December 27, 2007

Subject: Potential contaminated Apligraf Units manufactured by Organogenesis Inc.

Dear Doctor:

This letter is intended to inform you of important information regarding Apligraf units shipped to you on December 14 or 17, 2007. This involves units from **Apligraf Lot Number GS0711.20.01.2A. You have received Apligraf unit(s) from this Lot.**

Description of Issue
Apligraf Lot Number GS0711.20.01.2A was reported to have contamination in the agarose nutrient medium of some units retained at Organogenesis. Colonies were visually observed within the agarose. Preliminary microbiological testing identified the bacterial contaminant as a gram positive rod (bacillus) organism. A definitive identification of the organism will be provided to you by fax as soon as available.

Product Disposition
According to our records, your procedure date(s) for Apligraf from this Lot has already occurred and the product has likely been applied to a patient(s). If you *have not* applied the affected unit(s) to a patient, you should return unused product to Organogenesis Inc. for investigation. Information on product return can be obtained by contacting Organogenesis at the number below. Please maintain accurate and complete records of all returns and their disposition.

Clinical Implications
While the unit(s) you have received may not be contaminated, all standard wound care precautions should be used to assure the safety of the patient. If the affected units had been applied to a patient, it is recommended that you monitor the patient closely for any potential adverse events. Organogenesis recommends careful assessment of possible infection by observing for signs and symptoms of infection as well as treatment per your clinical discretion. Treatment options at your clinical

GS0711.20.02.2A
Lot # of
mary
Gilbertson
12/20/07

discretion include topical antibiotics, oral antibiotics or Apligraf removal. We hope that this information is helpful in managing care for your patient.

The quality of Apligraf and its safety are of the highest priority to Organogenesis. We are committed to providing complete information in a timely fashion and will contact you for patient follow up and reports of any adverse events that may have resulted subsequent to this Apligraf treatment.

In addition to this faxed letter, we are attempting to contact you by phone to provide information on this Apligraf Lot. **Although we will be attempting to contact you by phone today, It will be most efficient if you can contact us at 1 888 432-5252, Option # 2 (Medical Inquiries).**

To confirm receipt of this important communication, please sign and fax back this form to us at 781-401-1288.

Sincerely,

Patrick Bilbo
Vice President, Regulatory Affairs
(781) 401-1155

Recipient Signature: _____

Recipient Name: _____

PLEASE RETURN THIS LETTER SIGNED TO FAX #781-401-1288

Exhibit 6

From: Carol Gray [mailto:cgray@advancedbiohealing.com]
Sent: Monday, January 14, 2008 9:22 AM
Subject: Copy of the Recent Apligraf Recall Letter, Unparalled Safety Profile of Dermagraft.

Keeping You Informed:

Attached is the letter announcing the recent Apligraf recall from Organogenesis. Apligraf recalls have happened many times. (as reported to the FDA and documented on the FDA website).

Dermagraft has an unparalleled safety profile:

Advanced Biohealing, Inc. will not send any Dermagraft to customers, for use on their patients, until the **End of Production- USP Sterility Data** Testing Results are completed (conducted by an independent laboratory):

~end of production **USP Sterility Safety testing is a requirement *before* patient application with Dermagraft.** Dermagraft has a 5 month shelf life.

~end of production **USP Sterility Safety testing results for Apligraf are not obtained until *after* application to patients receiving Apligraf. This may put patients and their providers at risk.**

Apply Dermagraft with confidence! Safety Unparalleled!

Carol Gray
Advanced Technology Specialist
Mobile: 443 306 4762
EMail: cgray@advancedbiohealing.com

Right-click here to download pictures. To help protect your privacy, Outlook prevented automatic download of this picture from the Internet.

Customer Service: 1-877-337-6247

Right-click here to download pictures. To help protect your privacy, Outlook prevented automatic download of this picture from the Internet.

www.Dermagraft.com
www.AdvancedBioHealing.com

Exhibit 7

FDA Enforcement Reports (1991 - present)
1998
FDA ENFORCEMENT REPORT 98-20, 05/20/98

First Match

FDA ENFORCEMENT REPORT 98-20, 05/20/98

FDA ENFORCEMENT REPORT 98-20, 05/20/98

FDA ENFORCEMENT REPORT 98-20, 05/20/98

ENFORCE 05/20/98

RECALLS AND FIELD CORRECTIONS: FOODS -- CLASS I ==========

PRODUCT Basha Foods brand Taboule Salad packaged in 7 ounce and 12 ounce containers and in 5 pound bulk containers. Recall #F-491-8.
CODE All lots containing a three or four digit numeric code which begins with the number 2 or the number 02 and all lot numbers containing a three or four digit code which begins with 3 or 03 and is followed by two numbers ranging from 01 through 11.
MANUFACTURER Basha International Foods, Inc., Hamtramck, Michigan.
RECALLED BY Manufacturer, by visit beginning February 20, 1998. Firm-initiated recall complete. See also FDA press release P98-7, February 20, 1998.
DISTRIBUTION Illinois, Indiana, Michigan.
QUANTITY Approximately 1,250 pounds of taboule were distributed.
REASON Products may be contaminated with Listeria monocytogenes, Salmonella Arizona, Enterobacter cloacae, or Citrobacter freundii.

RECALLS AND FIELD CORRECTIONS: FOODS -- CLASS II ==========

PRODUCT Various bakery products:
1. 9 Inch Lemon Glazed Angelfood Cake, item code 80362, net weight 24 ounce
2. Dillons Signature 6 German Chocolate Brownies, item code 80375, net weight 8 ounce
3. Dillons Signature 6 Caramel Brownies, item Code 80376, net weight 8 ounce
4. 7 Inch German Chocolate Cake, item code 80312, net weight 26 ounce
5. Supreme Chocolate Cake, item code, 80346, net weight 20 ounce
6. 6 German Chocolate Cupcakes, item code 80371, net weight 10 ounce
7. 7 Inch Cherry White Cake, item code 80302, net weight 25 ounce

RECALLS AND FIELD CORRECTIONS: DEVICES -- CLASS II =========

PRODUCT IVAC MedSystem III Administration Sets, Model 28080E. Recall #Z-549-8. CODE Lot #801548. MANUFACTURER Sistemas Medico Alaris, SA DE C.V., Tijuana, Mexico. RECALLED BY Alaris Medical Systems, Inc., San Diego, California, by telephone and by letter on April 7, 1998. Firm-initiated recall ongoing.
DISTRIBUTION California, Florida, Illinois, Indiana, North Carolina, Wisconsin. QUANTITY 500 sets were distributed; firm estimated that 384 sets remained on market at time of recall initiation.
REASON Devices were mis-assembled. The tubing sections were reversed which could result in medication not being delivered and/or blood being drawn from the patients IV site.

PRODUCT << Dermagraft>> brand of Human Dermal Replacement, indicated for use as a temporary wound covering for surgically excised thermal burn wounds: a) << Dermagraft>> -TC; b) << Dermagraft>> . Recall #Z-571/572-8.
CODE Lot numbers: a) 101182 to 102722, non-sequential; b) 101720 to 12783, non-sequential.
MANUFACTURER Advanced Tissue Sciences, Inc. (ATS), La Jolla, California.
RECALLED BY Manufacturer, by letter on March 25, 1998, and by press release on March 30, 1998. Firm-initiated recall ongoing.
DISTRIBUTIO a) Nationwide and international; b) international.
QUANTITY a) 478 units; b) 281 units were distributed.
REASON Devices were manufactured and distributed from fetal bovine serum that did not meet firms specification for endotoxin.

UPDATE Recall #Z-514-8, Model TED 60T Portable Oxygen Monitor (Teledyne Electronic Technologies Analytical Instruments (TET/AI), City of Industry, California), which appeared in the April 22, 1998 Enforcement Report should read: RECALLED BY: Manufacturer, by letter on August 27, 1996. Firm-initiated recall ongoing.

RECALLS AND FIELD CORRECTIONS: DEVICES -- CLASS III ========

PRODUCT Ormco C-Type Release Module, for orthodontic headgear or neck pads:
a) Part No. 715-2020, medium (white) force;
b) Part No. 715-2021, heavy (gray) force.
Recall #Z-563/564-8.
CODE Lot numbers beginning with 7K, 7L, 7M, 8A, 8B, and 8C, covering lots manufactured in October, November and December 1997, and January, February, and March 1998.
MANUFACTURER Sybron Dental Specialties, Inc., Orange, California (responsible firm).
RECALLED BY Ormco Corporation, subsidiary of Sybron Dental Specialties, Inc., Glendora, California, by

Exhibit 8

FDA Enforcement Reports (1991 - present)
2003
Enforcement Report 03-24 June 11, 2003
RECALLS AND FIELD CORRECTIONS: DEVICES - CLASS II

* First Match

RECALLS AND FIELD CORRECTIONS: DEVICES - CLASS II

PRODUCT
a) Pulsar Multiprogrammable Pacemaker, DDD Model 970.
Recall # Z-0875-03;
b) Pulsar Multiprogrammable Pacemaker, DDD Model 972.
Recall # Z-0876-03;
c) Pulsar Multiprogrammable Pacemaker, DDD Model 976.
Recall # Z-0877-03;
d) Pulsar Multiprogrammable Pacemaker, DDDR Model 1270.
Recall # Z-0878-03;
e) Pulsar Multiprogrammable Pacemaker, DDDDR Model 1272.
Recall # Z-0879-03;
f) Pulsar Max Multiprogrammable Pacemaker.
Recall # Z-0880-03;
g) Pulsar Max II Multiprogrammable Pacemaker, DDDR
Model 1284. Recall # Z-0881-03;
h) Pulsar Max II Multiprogrammable Pacemaker, DDDR
Model 1286. Recall # Z-0882-03;
i) Discovery Multiprogrammable Pacemaker, DDDR
Model 1273. Recall # Z-0883-03;
j) Discovery Multiprogrammable Pacemaker, DDDR Model
1274. Recall # Z-0884-03;
k) Discovery II Multiprogrammable Pacemaker, DDD Model
981. Recall # Z-0885-03;
l) Discovery II Multiprogrammable Pacemaker, DDDR Model
1280. Recall # Z-0886-03;
m) Discovery II Multiprogrammable Pacemaker, DDDR Model
1283. Recall # Z-0887-03;
n) Meridian Multiprogrammable Pacemaker, DDDR Model
1275. Recall # Z-0888-03;
o) Meridian Multiprogrammable Pacemaker, DDDR Model
1286. Recall # Z-0889-03;
p) Insignia Plus Multiprogrammable Pacemaker, DDD Model
985. Recall # Z-0890-03;
q) Insignia Plus Multiprogrammable Pacemaker, DDD Model
986. Recall # Z-0891-03;
r) Insignia Plus Multiprogrammable Pacemaker, DDDR Model
1294. Recall # Z-0892-03;
s) Insignia Plus Multiprogrammable Pacemaker, DDDR Model
1295. Recall # Z-0893-03;

t) Insignia Extra Multiprogrammable Pacemaker, DDDR Model 1296. Recall # Z-0894-03;
u) Insignia Extra Multiprogrammable Pacemaker, DDDR Model 1297. Recall # Z-0895-03;
v) Insignia Extra Multiprogrammable Pacemaker, DDDR Model 1298. Recall # Z-0896-03;
w) Contak TR Multiprogrammable Pacemaker, DDDR Model 1241. Recall # Z-0897-03;

CODE
All Serial numbers.
RECALLING FIRM/MANUFACTURER
Guidant Corp-Cpi Division, St Paul, MN, by letter dated May 6, 2003. Firm initiated field correction is ongoing. A May 6, 2003 letter to physicians gave recommendations for avoiding the problem and indicated that software to prevent the problem would be introduced.
REASON
In a rare circumstance (fallback mode when high-rate atrial activity is detected), the battery gauge can over-estimate battery life.
VOLUME OF PRODUCT IN COMMERCE
298,000.
DISTRIBUTION
Nationwide, and Internationally.

PRODUCT
Neonatal GALT Test Kit, 960 tests per box, packaged under the PerkinElmer Life Sciences Inc. label, catalog No. NG-1100.
Recall # Z-0898-03.
CODE
Lot #115496, Exp. 11/1/03.
RECALLING FIRM/MANUFACTURER
PerkinElmer Life Sciences Inc., Norton, OH, by letter on January 8, 2003. Firm initiated recall is ongoing.
REASON
The Control Cards are incorrectly labeled such that the normal 'N' and abnormal 'A' values are reversed.
VOLUME OF PRODUCT IN COMMERCE
75 kits.
DISTRIBUTION
WI, AR, and MI.

PRODUCT
STA-Compact Hemostasis System with Cap piercing capability.
Recall # Z-0899-03.
CODE
All distributed units with cap piercing option.
RECALLING FIRM/MANUFACTURER
Diagnostica Stago, Inc., Parsippany, NY, by letters on March 5, 2003. Firm initiated recall is ongoing.
REASON
With maintenance of the STA line, the cap-piercing feature may involve potential risk of needle puncture injury.
VOLUME OF PRODUCT IN COMMERCE
137.
DISTRIBUTION

Nationwide.

PRODUCT
Misys Laboratory versions 5.2, 5.23 and 5.3 using Cache Database with linked CPUs. Recall # Z-0900-03.
CODE
Versions 5.2, 5.23 and 5.3.
RECALLING FIRM/MANUFACTURER
Misys Healthcare Systems, Tucson, AZ, by fax on June 26, 2002. Firm initiated recall is complete.
REASON
Customer reports that the processor failed to make patient report updates with two processors running in the LABB area.
VOLUME OF PRODUCT IN COMMERCE
38.
DISTRIBUTION
Nationwide.

PRODUCT
Trident Insert Impactor. Recall # Z-0901-03.
CODE
Catalog Number: 2111-0000.
RECALLING FIRM/MANUFACTURER
Stryker Howmedica Osteonics, Mahwah, NJ, by letters and acknowledgement forms on April 29, 2003. Firm initiated recall is ongoing.
REASON
The ball retaining sleeve on the Trident Insert Impactor can possibly disassemble.
VOLUME OF PRODUCT IN COMMERCE
1,758.
DISTRIBUTION
Internationally.

PRODUCT
a) Hill-Rom brand Affinity three birthing bed. Recall # Z-0902-03;
b) Hill-Rom brand Century+ series bed. Recall # Z-0903-03.
CODE
All units distributed between January 1, 1999 and July 1, 2002.
RECALLING FIRM/MANUFACTURER
Hill-Rom, Inc., Batesville, IN, by letters dated April 24, 2003. Firm initiated recall is ongoing.
REASON
Possible electrical shock hazard, as the power cord grounding pin may break off or become detached.
VOLUME OF PRODUCT IN COMMERCE
12,848.
DISTRIBUTION
Nationwide, and Internationally.

PRODUCT
<< Dermagraft>> , Human Fibroblast-Derived Dermal Substitute,
2 in. by 3 in. Recall # Z-0904-03.
CODE
Lot 116098.
RECALLING FIRM/MANUFACTURER
Smith and Nephew Wound Management (La Jolla), San Diego, CA, by telephone on or about May 2, 2003, and by

letter on May 7, 2003. Firm initiated recall is ongoing.
REASON
Did not meet finished device specifications for DNA criteria.
VOLUME OF PRODUCT IN COMMERCE
22.
DISTRIBUTION
Nationwide.

PRODUCT
a) Rascal Powered Scooters. Recall # Z-0909-03;
b) Chauffeur Powered Scooters. Recall # Z-0910-03.
CODE
a) Rascal Model Numbers 205, 215, 235, 245, 255, 305, 400.
There are 45,679 serial numbers.
b) Chauffeur Model Numbers are C205, C215, C235, C245, C255,
and C305. There are 45,679 serial numbers involved.
RECALLING FIRM/MANUFACTURER
Electric Mobility Corp., Sewell, NJ, by letter on February 7, 2003, and posted on the firms website on February 14, 2003. Firm initiated recall is ongoing.
REASON
The plastic tires may shatter if the tire is over-inflated and could cause serious injury.
VOLUME OF PRODUCT IN COMMERCE
45,679.
DISTRIBUTION
Nationwide, and Internationally.

PRODUCT
a) Inject 10 Coronary Control Syringe (CCS), 10ml.
Recall # Z-0912-03;
b) Custom Kit. Recall # Z-0913-03.
CODE
a) REF/CAT No.: CCX010, Lot No's. A257336, A258248, A258893, A263340; b) REF/CAT No.: K09-03442C. Lot No. A259058.
RECALLING FIRM/MANUFACTURER
Merit Medical Systems, Inc., South Jordan, UT, by letter on May 16, 2003. Firm initiated recall is ongoing.
REASON
Cracks in the syringe barrels could allow for air aspiration into the syringe barrel.
VOLUME OF PRODUCT IN COMMERCE
7,277 units.
DISTRIBUTION
Nationwide, and France, Malaysia, Taiwan, and Dominican Republic.

PRODUCT
10.5 Fr. Percor STAT-DL intra-Aortic Balloon Catheter Insertion
Kits which contain a Datascope 11.5 Fr. 11" introducer sheaths. These introducer sheaths include a hemostasis valve and a hub which work in conjunction with an introducer dilator. The introducer sheath, after it is dilated by the introducer dilator, is intended to assist the percutaneous insertion of the 10.5 Fr. Intra-Aortic Balloon catheter into the vasculature. Recall # Z-0916-03.
CODE
REF or Order #0684-00-0195-02; P/N #0684-00-0438; Lot #BRV; Exp. Date 03/03/05.
RECALLING FIRM/MANUFACTURER